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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
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EDWARD	D GRIE	FF	SACKEY, EBENEZER O		
HALE & DO	ORR LLP				
1455 PENN:	SYLVAN	IA AVE, NW	ART UNIT	PAPER NUMBER	
WASHINGTON, DC 20004				1626	
				DATE MAIL ED: 06/17/200	•

Please find below and/or attached an Office communication concerning this application or proceeding.

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILLING DATE OF THIS COMMUNICATION. Eacherison of time may be available used the previous of 3 CPR 1.136(a). In or event, however, may a reply be timely filed. Ethe period for may be specified above is less than thirty (30) days, as negly within the statutory minimum of thirty (30) days will be considered fitnely. Ethe period for reply specified above is less than thirty (30) days, as negly within the statutory minimum of thirty (30) days, as negly within the statutory minimum of thirty (30) days, as negly within the statutory minimum of thirty (30) days, as negly within the statutory minimum of thirty (30) days, as negly within the statutory minimum of thirty (30) days, as negly within the statutory minimum of thirty (30) days will be considered fitnely. Find period for reply specified above is the statutory period will apply and will applied all of the statutory within the section of the statutory minimum of the statutory minimum of thirty (30) days, as negly within the statutory minimum of thirty (30) days will be considered fitnely. Find period of the statutory within the section of the statutory minimum of the statut		Application No.	Applicant(s)
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Office Action Summary

DETAILED ACTION

Status of Claims

Claims 1-58 are pending.

This is a response to the office action mailed on 12/30/04.

The Petition from Restriction filed under 37 CFR 1.144 on 03/30/05 is acknowledged.

The Petition has been forwarded to the Special Programs Examiner for review and consideration. Decision on the Petition will be forwarded to applicants upon review.

Response to Restriction

Applicant's election of Group X in the reply filed on 03/30/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Response to Remarks

Applicant's arguments filed 03/30/05 have been fully considered but they are not deemed persuasive. Applicants argue that claims 1-4 are fully enabled and one of ordinary skill in the art could make and use the invention without undue experimentation, citing MPEP 2164.01(b) and 2164.04. In response, even tough 57 working examples are disclosed in the specification, again; only 4 examples pertain to the elected subject matter. Thus, the homogeneity of the 4 examples would provide no insight into structure-activity trends that need to be evaluated. According to MPEP § 2106.02, "it must be emphasized that arguments of counsel alone cannot take the place

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of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See *In re Budnick*, 537 F.2d at 538, 190 USPQ at 424; *In re Schulze*, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); *In re Cole*, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See *In re Knowlton*, 500 F.2d at 572, 183 USPQ at 37; *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979)."

Applicants next argue that the instant application is directed to the composition, Kits and methods of use of novel nitrosated nonsteroidal anti-inflammatory drugs and dose not involving receptor binding of the compounds of the invention. Contrary to applicant's assertion, NSAID's are known to inhibit the activity of for example cyclooxygenase, see page 6, lines 16-20, page 8, lines 19-31 etc. Thus, it involves receptor binding and considering the thousands, if not millions of compounds to be made, this constitute a large quantity of experimentation. As previously stated, only 4 compounds pertains to the elected subject matter. There is no reasonable basis for the assumption that the myriad of compounds embraced by formula (I) will all share the same biological properties. When considering the factors relating to a determination of non-enablement, if all the other factors point toward enablement, then the absence of working examples will not by itself render the invention non-enabled. In other words, lack of working examples or lack of evidence that the claimed invention works as described should not be the sole reason for rejecting the claimed invention on the

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grounds of lack of enablement. A single working example in the specification for a claimed invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be enabled. Note however, that a rejection stating that enablement is limited to a particular scope may be appropriate. See *In re Harwood*, 156 USPQ 673 in which the court upheld a rejection made for lack of utility, not enablement, in the unpredictable area of insect control, the court holding evidence regarding two species of insects did not support claims for insects generally. Thus, for the reasons of record, the rejection of claims 1-4 is being maintained.

The rejection of claims 1-4 under 35 USC 112, second paragraph, based on the numerous registry numbers has been withdrawn. However, the rejection of claim 4 is being maintained because it is not clear if applicants are claiming 1 or 2 or 3 nitrosated compounds. As previously pointed out, claim 1 permits one or more ONO₂ groups within X choices.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai. In re

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is

(571) 272-1600.

EOS

June 11, 2005

TAOFIQ SOLOLA

Dr. T. Solola

Primary Patent Examiner

Art Unit 1626, Group 1600

Technology Center 1